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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/616,718      | 07/14/2000  | Bert L. Vallee       | 11187-00001         | 5959             |

7590 03/13/2002

John P Iwanicki  
Banner & Witcoff Ltd  
28 State Street 28th Floor  
Boston, MA 02109

EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 03/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                 |               |
|------------------------------|-----------------|---------------|
| <b>Office Action Summary</b> | Application No. | Applicant(s)  |
|                              | 09/616,718      | VALLEE ET AL. |
| Examiner                     | Art Unit        |               |
| Cybille Delacroix-Muirheid   | 1614            |               |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 30 October 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-6 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 1 and 2 is/are allowed.

6) Claim(s) 3-6 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keung et al.
2. Claims 3-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,886,028.
3. Claims 3-6 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,624,910.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Response to Amendment*

The following is responsive to Applicant's amendment received Oct. 30, 2001.

No claims are cancelled. No new claims are added. Claims 1-6 are currently pending.

The previous rejection of claims 1-2 (**only**) under 35 USC 103(a) over the Keung et al. reference, set forth in paragraph 4 of the office action mailed Aug. 1, 2001, is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claims rejection under 35 USC 112, paragraph 2, set forth in paragraph 1 of the office action mailed Aug. 1, 2001, is **withdrawn** in view of Applicant's amendment and the remarks contained therein.

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The previous rejection of claims 1-2 under the judicially created doctrine of obviousness-type double patenting, set forth in paragraph 8 of the office action mailed Aug. 1, 2001, is withdrawn in view of Applicant's amendment and the remarks contained therein.

However, Applicant's arguments traversing (1) the remaining rejection of claims 3-5 under 35 USC 103(a) over Keung et al. (Paragraph 4 of the office action mailed Aug. 1, 2001) and (2) the previous rejections of claims 3-6 under the judicially created doctrine of obviousness-type double patenting have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed Aug. 1, 2001 with the following additional comment:

It is essentially Applicant's position that Keung et al. do not disclose the claimed methods which include the "use of aldehydes such as 5-hydroxyindole-3-acetaldehyde and 3,4-dihydroxyphenyl-3-acetaldehyde." Moreover, Applicant applies this same argument to the double patenting rejections. In other words, the double patenting rejections should be withdrawn because the US patents 5,886,028 and 5,624,910 do not claim methods which include the "use of aldehydes such as 5-hydroxyindole-3-acetaldehyde and 3,4-dihydroxyphenyl-3-acetaldehyde."

Said arguments have been considered but are not found persuasive.

First of all, Applicant's argument concerning the "use of aldehydes such as 5-hydroxyindole-3-acetaldehyde and 3,4-dihydroxyphenyl-3-acetaldehyde" is not commensurate in scope with claim 3. Applicant's argument is commensurate in scope with claim 1; however, and the claim

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has been found to be allowable. Therefore, claim 6, which recites the very limitation Applicant is arguing is now objected to and claim 3 would be found allowable over the Keung et al. reference if Applicant amended claim 3 to contain the limitations of claim 6.

Otherwise, claim 3, as amended, remains obvious over the Keung et al. reference. The Examiner maintains that it would have been obvious to one of ordinary skill in the art to administer daidzin and its analogs to a human because in view of the successful reduction of ethanol intake by hamsters as a result of ALDH-2 inhibition, one of ordinary skill in the art would reasonably expect daidzin and its analogs to effectively inhibit ALDH-2 and thus reduce alcohol consumption in humans. With respect to the claimed increase of “an aldehyde” (claim 3), such an increase would have been obvious because the prior art discloses substantially similar methods and compounds.

Concerning the double patenting rejection, Applicant’s arguments concerning the “use of aldehydes such as 5-hydroxyindole-3-acetaldehyde and 3,4-dihydroxyphenyl-3-acetaldehyde” are not commensurate in scope with the claims. Moreover, even if this limitation were in claim 3, the double patenting rejections would stand. Applicant has not argued how the limitation regarding the use of aldehydes such as 5-hydroxyindole-3-acetaldehyde and 3,4-dihydroxyphenyl-3-acetaldehyde render the claimed inventive method patentably distinct from the claimed methods of USPN’s 5,886,028 and 5,624,910. The scope of the claims of the instant application continue to overlap with the claims of USPN ‘910 and ‘028.

It for these reasons that the rejections stand.

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***New Ground(s) of Rejection***

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 3-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Vallee et al., 5,624,910 or Vallee et al., 5,204,369.

Vallee et al. '910 disclose methods for treating alcohol consumption or alcohol abuse, the methods comprising administering an effective amount of daidzin to reduce alcohol consumption. Please see the abstract; col. 10, lines 37-45; claims 1-6.

Vallee et al., '369 disclose methods for treating alcohol dependence or abuse, the methods comprising administering effective amounts of daidzin. Please see the abstract; col. 14, lines 63-67; col. 16, lines 22-30; col. 21, lines 25-45.

The claims are anticipated by Vallee et al., '910 or '369 because they disclose administration of an identical active agent, daidzin, to a host, i.e. a human, using Applicant's claimed method steps. Accordingly, the increased concentrations of an aldehyde such as those in claim 6 would be inherent.

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***Allowable Subject Matter***

Claims 1-2 are free from the prior art because the prior art does not disclose or fairly suggest Applicant's claimed method.

***Conclusion***

Claims 3-6 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



March 8, 2002



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600